

## URGENT FIELD SAFETY NOTICE



Date of Letter Deployment

GE HealthCare Ref. #32102

To: Healthcare Administrator / Risk Manager  
Director of Neonatology/L and D/Nurse Manager  
Director of Biomedical Engineering

RE: **Giraffe and Panda Warmers with Integrated Resuscitation System (iRes) and Giraffe Stand-alone Infant Resuscitation Systems**

### Safety Issue

GE HealthCare has become aware of a potential issue involving the air-oxygen blender knob shaft on certain integrated and stand-alone Resuscitation systems. In some cases, the blender knob shaft can loosen, which can affect the delivered oxygen concentration. If this occurs, the system can deliver an oxygen concentration that does not match the intended concentration set by the user, potentially resulting in hypoxia or hyperoxia in the patient.

### Actions to be taken by Customer/User

1. Inspect all of your Giraffe, Panda Warmers with Integrated Resuscitation System (iRes), and Giraffe Stand-alone Infant Resuscitation System devices following the instructions in Appendix 1 to determine if the device has an affected blender listed in Appendix 2.
2. If the device has an affected blender listed in Appendix 2, remove the unit from patient use and contact a GE HealthCare Service Representative at the number listed below.
3. If a device with an affected blender must be used prior to being corrected by GE HealthCare, follow the instructions below:
  - A. Follow the instructions in the Panda Warmer and/or Giraffe Warmer User Manuals, including all pre-use checkout instructions (M1110737 and M1110734 Chapter 8 Pre-use checkout and setup procedures) and the Giraffe™ Stand-alone Infant Resuscitation System User Manual (M1226780 Chapters 4 and 5 Checkout and Use). These manuals also include the following requirements and warnings:
    - Pre-use checkout: Before each operation, inspect the resuscitation system for damage, such as broken knobs and fittings or gauges with indicator needles that are not at 0.
    - Do not do the pre-use checkout procedure, service, or calibrate the device with the patient in the device. Make sure all pre-use checkout procedure steps are correctly completed before each patient use. If a step fails, do not use the device.
  - B. Perform the blender Multipoint Oxygen Concentration Check as described in Section 2.5.1 of the Service Manual M1128929.

- C. If the pre-use checkout passes and the Multipoint Oxygen Concentration Check meets specifications, GE HealthCare recommends oxygen concentration should be verified with an independent oxygen analyzer on a frequent basis until the unit is corrected.
- D. If the pre-use check does not pass (e.g., the blender knob is loose) or the Multipoint Oxygen Concentration Check does not meet specifications, remove the unit from patient use.

Note: User and service manuals are available on the Customer Documentation Portal:  
<https://www.gehealthcare.com/support/manuals>.

- 4. Please evaluate existing service stock for affected blenders. The blender model number and serial number are visible on the packaging. The serial number is visible on the blender. Quarantine any blenders with model number M1091607-R if the serial number is listed in Appendix 2.
- 5. Please complete and return the attached Acknowledgement Form electronically via FMI 32102 Digital CRF or print, fill out manually, scan, and email to **Confidential business information**

Please ensure all potential users in your facility are made aware of this safety notification and the recommended actions.

Please retain this document for your records.

### Affected Product Details

Below listed products are impacted only if M1091607-R blender was installed during the last Preventive Maintenance. No action is required for units where an M1091607-X or M1091607 was used during last Preventive Maintenance. See the affected blender serial number list in Appendix 2.

| Product                                                     | Ref#                                    | GTIN Number                                                 |
|-------------------------------------------------------------|-----------------------------------------|-------------------------------------------------------------|
| Giraffe™ Stand-alone Infant Resuscitation System            | 2082663-001<br>2082663-002<br>M1241424* | 00840682100151<br>00840682100175                            |
| Giraffe™ Warmer with Integrated Resuscitation System (iRes) | M1118179                                | 00840682103923                                              |
| Panda Warmer with Integrated Resuscitation System (iRes)    | M1112198                                | V2.0 (Hybrid)<br>00840682152716<br>V1.0 (US) 00840682152709 |
| Panda Freestanding warmer                                   | 2063568-001                             | 00840682103916                                              |
| Service Blender Includes Standoffs and Knob                 | M1091607-R                              | NA                                                          |

\*NOTE: Some products were shipped prior to the implementation of UDI and may not contain a Global Trade Item Number (GTIN)

### Intended Use:

The Integrated Resuscitation and Standalone Infant Resuscitation Systems provides the basic equipment required for pulmonary resuscitation of infants. Pulmonary resuscitation includes

practices necessary to establish a clear airway and provide oxygen or air/oxygen mixtures during manual ventilation to the infant. These are clinical practices that represent the established standard of care. Resuscitation may be required whenever an infant fails to establish effective, adequate breathing patterns necessary to meet tissue oxygen demands and/or to rid the body of carbon dioxide.

### **Product Correction**

GE HealthCare will correct all affected products at no cost to you. A GE HealthCare representative will contact you to arrange for the correction.

### **Contact Information**

If you have any questions or concerns regarding this notification, please contact GE HealthCare Service or your local Service Representative.

### **Confidential business information**

[Redacted]

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact GE HealthCare per the contact information above.

Sincerely,



Laila Gurney  
Chief Quality & Regulatory Officer  
GE HealthCare



Scott Kelley  
Chief Medical & Safety Officer  
GE HealthCare

## MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT

### RESPONSE REQUIRED

**Please complete this form and return it to GE HealthCare promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice.**

Facility Name: \_\_\_\_\_

Street Address: \_\_\_\_\_

City/State/ZIP/Country: \_\_\_\_\_

Customer Email Address: \_\_\_\_\_

Customer Phone Number: \_\_\_\_\_

☐ No affected serial numbers were identified at this Facility

☐ Affected Serial Numbers:

| Blender Serial Number | Serial # of the Giraffe and Panda Warmers with Integrated Resuscitation System (iRes) and or Giraffe Stand-alone Infant Resuscitation Systems |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|
|                       |                                                                                                                                               |
|                       |                                                                                                                                               |
|                       |                                                                                                                                               |
|                       |                                                                                                                                               |
|                       |                                                                                                                                               |

By signing this form, we acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have informed all potential users and have taken and will take appropriate actions in accordance with that Notification.

**Please provide the name of the individual with responsibility who completed this form.**

Signature: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Position/Job Title: \_\_\_\_\_

Date (DD/MM/YYYY): \_\_\_\_\_

**To complete this form electronically, please scan the QR Code below or click this link:**

Confidential business information



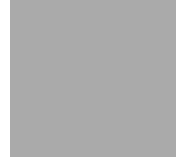
Confidential business information



**To complete this form via email, scan or take a photo of the completed form and email to:**

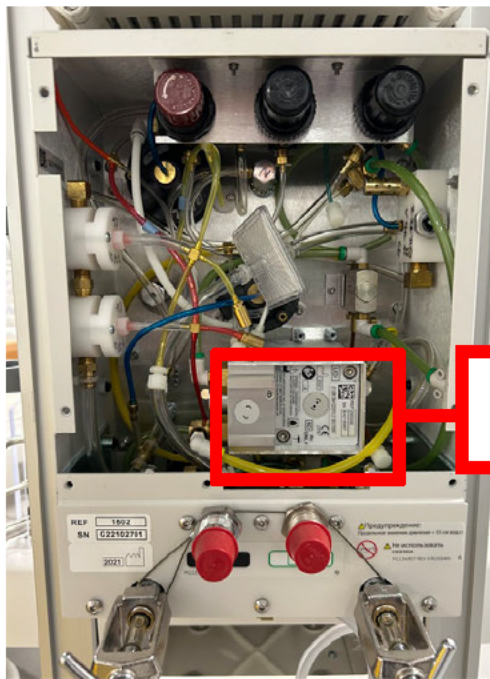
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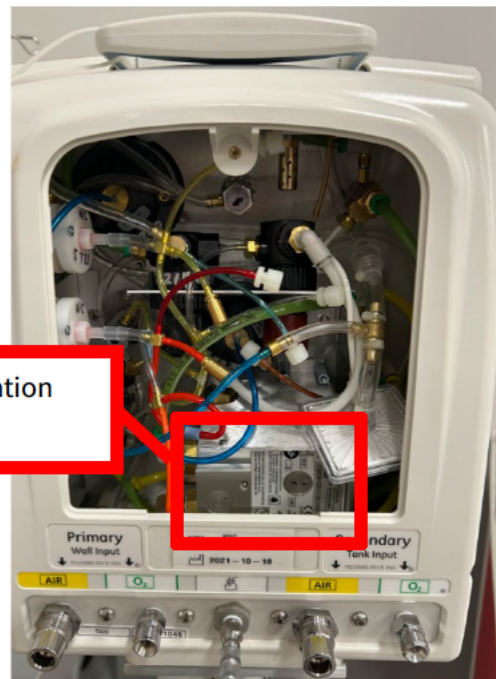


## Appendix 1: Blender Identification Procedure

To determine if you have an affected blender serial number, remove the back panel of the resuscitation system. The serial number will be visible on the back of the blender. Review Appendix 2 to confirm if the serial number is listed as an affected blender. Record the information as required in the Medical Device Notification Acknowledgement Form.



Blender location



**Figure 2:** Giraffe™ Stand-alone Infant Resuscitation System with the back panel removed.



Blender serial number

**Figure 3:** Picture of the location of the blender serial number.

## Appendix 2: Affected Blender Serial Number List

Note: Blenders with serials numbers not in this list are not affected.

|            |          |          |          |          |          |
|------------|----------|----------|----------|----------|----------|
| 12105790   | 136W08B  | 355P09B  | B1102015 | B1202740 | B1208736 |
| 7979700385 | 141J09B  | B1003093 | B1102405 | B1203408 | B1208739 |
| 002I08B    | 142W09B  | B1003112 | B1102571 | B1203414 | B1208759 |
| 002X08B    | 144J08B  | B1003124 | B1103145 | B1203520 | B1209463 |
| 008S10B    | 144N08B  | B1003140 | B1103159 | B1203557 | B1209467 |
| 008Y09B    | 149Q09B  | B1003143 | B1103251 | B1203643 | B1209641 |
| 013S09B    | 163608B  | B1003147 | B1103256 | B1203892 | B1209642 |
| 016A09B    | 169D08B  | B1003153 | B1103422 | B1203905 | B1209647 |
| 019J09B    | 169G08B  | B1003343 | B1103434 | B1203909 | B1209796 |
| 037E08B    | 169H08B  | B1003452 | B1103576 | B1203913 | B1209956 |
| 038D10B    | 172308B  | B1003550 | B1103710 | B1203917 | B1211743 |
| 038N08B    | 175P08B  | B1003867 | B1103850 | B1204710 | B1211784 |
| 042F10B    | 185I08B  | B1003944 | B1103856 | B1205518 | B1211907 |
| 042S10B    | 185Q08B  | B1004844 | B1103968 | B1205537 | B1212670 |
| 042T10B    | 189808B  | B1004861 | B1104440 | B1205804 | B1212683 |
| 045808B    | 189A09B  | B1005029 | B1104441 | B1205820 | B1212706 |
| 047I08B    | 189C08B  | B1005036 | B1104450 | B1206201 | B1212817 |
| 047J08B    | 189F09B  | B1005422 | B1104651 | B1206909 | B1300102 |
| 054C10B    | 193L08B  | B1005534 | B1104658 | B1206948 | B1300110 |
| 054I10B    | 193N08B  | B1005560 | B1104764 | B1207178 | B1300126 |
| 054L10B    | 195D09B  | B1005571 | B1105179 | B1207180 | B1300416 |
| 054N09B    | 195E09B  | B1005839 | B1105180 | B1207181 | B1300430 |
| 054O09B    | 195J09B  | B1006102 | B1105232 | B1207189 | B1300805 |
| 054U10B    | 195K09B  | B1006304 | B1105244 | B1207201 | B1300812 |
| 055D09B    | 198H08B  | B1006935 | B1105418 | B1207202 | B1300830 |
| 055V09B    | 210U09B  | B1007078 | B1105548 | B1207215 | B1300858 |
| 061K09B    | 218N09B  | B1007220 | B1105806 | B1207240 | B1300919 |
| 068W10B    | 219C09B  | B1007262 | B1106117 | B1207308 | B1302107 |
| 077M09B    | 219K09B  | B1007383 | B1106789 | B1207555 | B1302132 |
| 078M09B    | 220E08B  | B1007528 | B1106812 | B1208045 | B1302133 |
| 078S09B    | 226F08B  | B1007605 | B1106823 | B1208066 | B1302180 |
| 084I10B    | 244L09B  | B1101215 | B1107074 | B1208067 | B1302527 |
| 084J10B    | 260X09B  | B1101224 | B1107357 | B1208068 | B1302583 |
| 092G08B    | 266M08B  | B1101241 | B1107360 | B1208069 | B1302593 |
| 099F08B    | 267808B  | B1101445 | B1107581 | B1208102 | B1302945 |
| 100E08B    | 280F09B  | B1101446 | B1107658 | B1208104 | B1302983 |
| 100R08B    | 281H09B  | B1101862 | B1201361 | B1208141 | B1303084 |
| 104A09B    | 285J07B  | B1101869 | B1201601 | B1208296 | B1303098 |
| 133D08B    | 295J09B  | B1101998 | B1202187 | B1208702 | B1303453 |
| 136708B    | 338K07B  | B1102011 | B1202199 | B1208729 | B1303454 |
| B1303492   | B1310237 | B1404760 | B1408533 | B1503611 | B1505842 |
| B1303581   | B1400022 | B1404786 | B1409022 | B1503644 | B1505843 |

|           |           |           |           |           |           |
|-----------|-----------|-----------|-----------|-----------|-----------|
| B1303854  | B1400237  | B1404925  | B1409048  | B1503665  | B1505879  |
| B1303868  | B1400243  | B1404981  | B1409051  | B1503667  | B1505884  |
| B1304069  | B1400264  | B1405020  | B1409052  | B1503673  | B1505899  |
| B1304357  | B1400278  | B1405213  | B1409053  | B1503687  | B1505954  |
| B1304374  | B1400292  | B1405218  | B1409324  | B1503698  | B1505981  |
| B1304450  | B1400760  | B1405542  | B1409509  | B1504073  | B1505990  |
| B1304518  | B1400771  | B1405558  | B1409533  | B1504076  | B1505992  |
| B1304564  | B1400946  | B1405574  | B1409546  | B1504078  | B1505994  |
| B1304570  | B1401757  | B1405576  | B1409569  | B1504339  | B1505997  |
| B1304574  | B1401785  | B1405577  | B1409588  | B1504538  | B1506198  |
| B1304751  | B1401893  | B1405589  | B1409590  | B1504754  | B1506203  |
| B1305163  | B1402142  | B1405601  | B1409722  | B1504755  | B1506208  |
| B1305175  | B1402162  | B1405608  | B1409731  | B1504761  | B1506209  |
| B1305213  | B1402168  | B1405621  | B1501314  | B1504765  | B1506215  |
| B1305215  | B1402196  | B1405622  | B1501652  | B1504800  | B1506216  |
| B1305337  | B1402198  | B1405629  | B1501657  | B1504919  | B1506220  |
| B1305363  | B1402224  | B1405630  | B1501675  | B1504951  | B1506237  |
| B1305523  | B1402504  | B1405649  | B1501686  | B1504999  | B1506240  |
| B1306066  | B1402854  | B1405688  | B1501693  | B1505000  | BX1101219 |
| B1306068  | B1403053  | B1405909  | B1502040  | B1505085  | BX1501179 |
| B1306078  | B1403079  | B1405998  | B1502054  | B1505090  | BX1501323 |
| B1306902  | B1403128  | B1406104  | B1502157  | B1505091  | BX1501350 |
| B1307502  | B1403140  | B1406186  | B1502195  | B1505093  | BX1501429 |
| B1307514  | B1403155  | B1406190  | B1502200  | B1505096  | BX1501514 |
| B1307526  | B1403230  | B1406191  | B1502616  | B1505301  | BX1501668 |
| B1307553  | B1403366  | B1406196  | B1502655  | B1505304  | BX1501686 |
| B1307814  | B1403769  | B1406197  | B1502656  | B1505527  | BX1501849 |
| B1308177  | B1403778  | B1406432  | B1502659  | B1505529  | BX1501857 |
| B1308332  | B1403880  | B1406441  | B1502668  | B1505536  | BX1501865 |
| B1308340  | B1403911  | B1406482  | B1502675  | B1505570  | BX1501894 |
| B1308362  | B1403914  | B1406506  | B1502887  | B1505573  | BX1501895 |
| B1308367  | B1403934  | B1406507  | B1502892  | B1505576  | BX1501897 |
| B1308874  | B1403952  | B1406518  | B1502894  | B1505624  | BX1501899 |
| B1309123  | B1404430  | B1406528  | B1502899  | B1505636  | BX1501900 |
| B1309124  | B1404469  | B1406537  | B1503153  | B1505637  | BX1501903 |
| B1309135  | B1404473  | B1406599  | B1503210  | B1505638  | BX1501911 |
| B1309139  | B1404480  | B1407065  | B1503224  | B1505655  | BX1502336 |
| B1309150  | B1404481  | B1407092  | B1503229  | B1505656  | BX1502340 |
| B1309683  | B1404495  | B1407755  | B1503240  | B1505825  | BX1502392 |
| B1309705  | B1404723  | B1407776  | B1503274  | B1505839  | BX1502705 |
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| B1310226  | B1404754  | B1408525  | B1503608  | B1505841  | BX1502739 |
| BX1502748 | BX1602418 | BX1603671 | BX1701752 | BX1703725 | BX1705941 |
| BX1502751 | BX1602465 | BX1603677 | BX1701779 | BX1703730 | BX1706088 |
| BX1502753 | BX1602497 | BX1603680 | BX1701808 | BX1703856 | BX1706123 |

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|-----------|-----------|-----------|-----------|-----------|-----------|
| BX1502759 | BX1602527 | BX1603687 | BX1701864 | BX1703949 | BX1706139 |
| BX1502764 | BX1602586 | BX1603689 | BX1701990 | BX1704125 | BX1801007 |
| BX1502766 | BX1602614 | BX1603694 | BX1702032 | BX1704128 | BX1801011 |
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| BX1601032 | BX1602653 | BX1604340 | BX1702057 | BX1704183 | BX1801102 |
| BX1601044 | BX1602746 | BX1604353 | BX1702067 | BX1704220 | BX1801245 |
| BX1601050 | BX1602764 | BX1604421 | BX1702070 | BX1704279 | BX1801354 |
| BX1601062 | BX1602779 | BX1604532 | BX1702321 | BX1704481 | BX1801438 |
| BX1601063 | BX1602818 | BX1604659 | BX1702357 | BX1704518 | BX1801446 |
| BX1601066 | BX1602823 | BX1604819 | BX1702372 | BX1704529 | BX1801456 |
| BX1601268 | BX1602825 | BX1605003 | BX1702375 | BX1704599 | BX1801537 |
| BX1601277 | BX1602830 | BX1605014 | BX1702461 | BX1704692 | BX1801546 |
| BX1601286 | BX1602839 | BX1605016 | BX1702467 | BX1704848 | BX1801586 |
| BX1601307 | BX1602850 | BX1605119 | BX1702557 | BX1704854 | BX1801589 |
| BX1601322 | BX1602856 | BX1605122 | BX1702568 | BX1704859 | BX1801590 |
| BX1601392 | BX1602857 | BX1605127 | BX1702573 | BX1704860 | BX1801591 |
| BX1601394 | BX1602860 | BX1605252 | BX1702602 | BX1704962 | BX1801593 |
| BX1601397 | BX1602862 | BX1605255 | BX1702646 | BX1704965 | BX1801598 |
| BX1601432 | BX1602908 | BX1605294 | BX1702665 | BX1704971 | BX1801600 |
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| BX1601518 | BX1602925 | BX1605701 | BX1702874 | BX1705061 | BX1801608 |
| BX1601519 | BX1602932 | BX1605835 | BX1702894 | BX1705155 | BX1801610 |
| BX1601521 | BX1602934 | BX1606122 | BX1703020 | BX1705323 | BX1801611 |
| BX1601523 | BX1602935 | BX1606148 | BX1703023 | BX1705376 | BX1801663 |
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| BX1601526 | BX1602969 | BX1701008 | BX1703194 | BX1705484 | BX1802029 |
| BX1601527 | BX1602986 | BX1701117 | BX1703244 | BX1705498 | BX1802091 |
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| BX1601538 | BX1603014 | BX1701460 | BX1703369 | BX1705567 | BX1802250 |
| BX1601541 | BX1603033 | BX1701471 | BX1703504 | BX1705687 | BX1802299 |
| BX1601797 | BX1603090 | BX1701477 | BX1703506 | BX1705769 | BX1802314 |
| BX1601881 | BX1603111 | BX1701484 | BX1703573 | BX1705783 | BX1802404 |
| BX1601941 | BX1603115 | BX1701597 | BX1703681 | BX1705823 | BX1802490 |
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| BX1602083 | BX1603356 | BX1701648 | BX1703696 | BX1705872 | BX1802895 |
| BX1602195 | BX1603377 | BX1701666 | BX1703703 | BX1705920 | BX1802902 |
| BX1602315 | BX1603553 | BX1701674 | BX1703715 | BX1705932 | BX1802934 |
| BX1802972 | BX1803857 | BX1805745 | BX1901981 | BX1903022 | BX1904357 |
| BX1803013 | BX1803881 | BX1805770 | BX1901992 | BX1903072 | BX1904374 |
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|-----------|-----------|-----------|-----------|-----------|-----------|
| BX1803049 | BX1803962 | BX1805871 | BX1902036 | BX1903235 | BX1904555 |
| BX1803058 | BX1804040 | BX1805876 | BX1902040 | BX1903247 | BX1904569 |
| BX1803061 | BX1804206 | BX1805918 | BX1902054 | BX1903255 | BX1904570 |
| BX1803065 | BX1804219 | BX1805923 | BX1902066 | BX1903357 | BX1904571 |
| BX1803097 | BX1804265 | BX1805937 | BX1902076 | BX1903365 | BX1904573 |
| BX1803107 | BX1804290 | BX1805941 | BX1902125 | BX1903367 | BX1904667 |
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| BX1803206 | BX1804426 | BX1806251 | BX1902166 | BX1903424 | BX1904846 |
| BX1803207 | BX1804439 | BX1806254 | BX1902170 | BX1903427 | BX1904927 |
| BX1803228 | BX1804443 | BX1806302 | BX1902194 | BX1903434 | BX1904935 |
| BX1803279 | BX1804508 | BX1806445 | BX1902211 | BX1903447 | BX1905048 |
| BX1803316 | BX1804548 | BX1806636 | BX1902235 | BX1903525 | BX1905103 |
| BX1803331 | BX1804586 | BX1901006 | BX1902297 | BX1903602 | BX1905106 |
| BX1803334 | BX1804655 | BX1901149 | BX1902300 | BX1903624 | BX1905112 |
| BX1803346 | BX1804660 | BX1901170 | BX1902302 | BX1903650 | BX1905116 |
| BX1803352 | BX1804761 | BX1901173 | BX1902426 | BX1903688 | BX1905124 |
| BX1803354 | BX1804836 | BX1901176 | BX1902448 | BX1903722 | BX1905130 |
| BX1803368 | BX1804870 | BX1901178 | BX1902475 | BX1903819 | BX1905155 |
| BX1803369 | BX1804950 | BX1901206 | BX1902557 | BX1903845 | BX1905168 |
| BX1803371 | BX1804960 | BX1901227 | BX1902562 | BX1903851 | BX1905174 |
| BX1803373 | BX1805024 | BX1901229 | BX1902572 | BX1903875 | BX1905175 |
| BX1803381 | BX1805032 | BX1901233 | BX1902576 | BX1903878 | BX1905176 |
| BX1803440 | BX1805035 | BX1901254 | BX1902579 | BX1903947 | BX1905220 |
| BX1803517 | BX1805142 | BX1901299 | BX1902605 | BX1903952 | BX1905238 |
| BX1803518 | BX1805259 | BX1901323 | BX1902679 | BX1903971 | BX1905245 |
| BX1803635 | BX1805260 | BX1901429 | BX1902692 | BX1903982 | BX1905247 |
| BX1803654 | BX1805322 | BX1901555 | BX1902746 | BX1904005 | BX1905252 |
| BX1803690 | BX1805404 | BX1901614 | BX1902749 | BX1904081 | BX1905253 |
| BX1803709 | BX1805411 | BX1901719 | BX1902809 | BX1904093 | BX1905254 |
| BX1803741 | BX1805418 | BX1901881 | BX1902828 | BX1904124 | BX1905258 |
| BX1803759 | BX1805423 | BX1901889 | BX1902847 | BX1904148 | BX1905308 |
| BX1803769 | BX1805445 | BX1901892 | BX1902874 | BX1904170 | BX1905313 |
| BX1803771 | BX1805449 | BX1901901 | BX1902907 | BX1904224 | BX1905390 |
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| BX1905976 | BX2001620 | BX2002290 | BX2003151 | BX2004043 | BX2004454 |

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| BX2001083 | BX2001789 | BX2002442 | BX2003621 | BX2004094 | BX2004500 |
| BX2001085 | BX2001891 | BX2002476 | BX2003641 | BX2004100 | BX2004509 |
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| BX2001113 | BX2001962 | BX2002565 | BX2003675 | BX2004138 | BX2004625 |
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